

~~“(1) IN GENERAL.—SUBSECTIONS (A) AND (B) GENERAL.—Subsection (a) shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—~~

~~“(A) is adopted or authorized under the authority of, or authorized to comply with, any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under any other Federal law;~~

~~“(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or~~

~~“(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, unless the action taken by the State or political subdivision of a State— except to the extent that the action—~~

~~“(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and~~

~~“(ii)(I) addresses the same hazards and or exposures, with respect to the same conditions of use, as is already required by a decision by the Administrator under section 5 or 6;~~

~~“(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, but is inconsistent with the action determination of the Administrator under section 6(c)(1)(A) or a rule promulgated by the Administrator under section 6(d); or~~

~~“(III)“(II) would cause a violation of the applicable action by the Administrator under section 5 or 6; or~~

“(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

“(A) is adopted **or authorized** under the authority of, ~~or authorized to comply with, any other Federal law or adopted for the purpose of satisfying or obtaining authorization or approval under any other Federal law;~~

“(B) implements a reporting, monitoring, **disclosure**, or other information ~~collection~~ obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; ~~or~~

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~~“(III)“(II) would cause a violation of the applicable action by the Administrator under section 5 or 6; or~~

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, April 09, 2015 5:13 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: EPA TA

Sven,

Here are a few things we would greatly appreciate some EPA TA on. We may need to discuss some further so if a phone call would be helpful please just let me know and thanks in advance for the help. I am also happy to work with you to help facilitate a call between your folks and some interested parties on the articles language if you think that would help.

Dimitri

Articles

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- Draft staff language - New 3A(h)(2)(C)(ii)(III): “ when considering the regulation of an article, or a category of articles, in a rulemaking under section 6, clearly describe the exposure or exposures to the chemical substance determined by the Administrator to be associated with such articles or categories of articles.”

Preemption

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Exceptions/No Preemption of State Statutes and Administrative Actions – these two provisions other than their intro paragraphs are identical. The request for clarification and TA comes from subsection A in both 1 and 2. I have concern that “for the purpose of satisfying or obtaining authorization or approval under any other federal law” is incredibly broad and could leave loop holes for states to regulate TSCA regulated chemical substances in ways inconsistent with EPA decisions under the law. If EPA for example (possibly not the most eloquent or well thought out example) found a product safe for use in an aerosol application yet a state banned it under their state law to comply with the CAA to reduce VOCs or some other air pollutant – maybe it is one option the state could take “for the purpose of satisfying or obtaining authorization or approval” but it may be one of a range of options – why should that be inconsistent with an EPA TSCA decision. I think at a minimum I would prefer language stating the state level restriction is “necessary” to satisfy or obtain authorization or approval rather than “for the purpose of.”

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/2/2015 7:50:13 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Nomenclature

Michal – checking on Friday availability. Thanks,
Sven

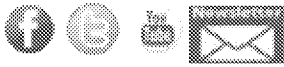
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, November 02, 2015 2:47 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Nomenclature

Could we set up a quick call, maybe for Friday if you guys are available? thanks

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, October 28, 2015 6:15 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Nomenclature

Michal,
Attached please find the requested technical assistance on nomenclature. Please let me know if you would like a call to discuss the TA. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2015 3:01:40 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA Request

For the call at 2pm today, please call Personal Phone / Ex. 6 code Personal Phone / Ex. 6 Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 10:57 AM
To: Karakitsos, Dimitri (EPW); Kaiser, Sven-Erik
Subject: RE: SEPW TSCA TA Request

Same. Do you have a good call-in number we can use?

From: Karakitsos, Dimitri (EPW)
Sent: Friday, April 10, 2015 10:56 AM
To: 'Kaiser.Sven-Erik@epa.gov'; Black, Jonathan (Tom Udall)
Subject: Re: SEPW TSCA TA Request

Works for me.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 10, 2015 10:51 AM
To: Black, Jonathan (Tom Udall); Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

Jonathan and Dimitri,
Any availability around 2-3 pm today for a call? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, April 10, 2015 9:58 AM
To: Kaiser, Sven-Erik; Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA Request

We're under a quick turn-around time-constraint. Perhaps we can get on the phone to discuss some of these things to facilitate a faster discussion?

From: Kaiser, Sven-Erik [<mailto:Kaiser.Sven-Erik@epa.gov>]

Sent: Friday, April 10, 2015 9:31 AM

To: Karakitsos, Dimitri (EPW)

Cc: Black, Jonathan (Tom Udall)

Subject: SEPW TSCA TA Request

Dimitri,

Thank you for the technical assistance request. We'll get to work on it. Please let me know your sense of priority on this request as we are preparing for a House TSCA hearing on Tuesday, April 14. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]

Sent: Thursday, April 09, 2015 5:13 PM

To: Kaiser, Sven-Erik

Cc: Black, Jonathan (Tom Udall)

Subject: EPA TA

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Articles

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Waiver – in our State Waivers we have two separate provisions that require a showing of a “compelling state or local” condition or interest. Those provisions were not intended to mean that the state would have to show some different exposures or unique conditions to meet that requirement, it was simply that they had a genuine concern with the substance that led them to request the waiver. Is there some way to clarify?

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2015 2:51:14 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA Request

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Sent: 4/10/2015 1:30:31 PM
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CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
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Sent: 7/7/2015 1:07:39 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Joseph, Avenel (Markey) [Avenel_Joseph@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on SNURs
Attachments: Carpet SNUR Final.pdf; Bundle SNUR for TA.pdf

Michal,

This responds to your technical assistance request on SNURs. Attached are two final SNURs that describe the section 5 considerations and discuss the rationale for lifting the articles exemption.

- 1) PFCs in Carpets: the relevant portions start in section III on p. 62445 and continue through section IV on p. 62447.
- 2) Benzidine Dyes (and other chemicals): the relevant portions for the benzidine dyes can be found in section III on p. 77893 and section IV on p. 77894

Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, June 25, 2015 3:56 PM
To: Kaiser, Sven-Erik
Cc: Joseph, Avenel (Markey)
Subject: TA request - SNURs

Hi Sven

I'm looking for a couple of illustrative examples of SNURs that show how the section 5 considerations are typically described. It would be great to get one that describes the basis for removing the exemption for articles too.

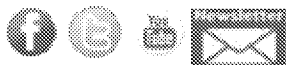
Thanks
michal

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

- (A) the projected volume of manufacturing and processing of a chemical substance,
- (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,
- (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and
- (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



As used in this exclusion, "anti-personnel landmine" means any mine placed under, on, or near the ground or other surface area, or delivered by artillery, rocket, mortar, or similar means or dropped from an aircraft and which is designed to be detonated or exploded by the presence, proximity, or contact of a person; any device or material which is designed, constructed, or adapted to kill or injure and which functions unexpectedly when a person disturbs or approaches an apparently harmless object or performs an apparently safe act; any manually-emplaced munition or device designed to kill, injure, or damage and which is actuated by remote control or automatically after a lapse of time.

Note 16: The radar systems described are controlled in USML Category XI(a)(3)(i) through (v). As used in this entry, the term "systems" includes equipment, devices, software, assemblies, modules, components, practices, processes, methods, approaches, schema, frameworks, and models.

Note 17: This exclusion does not apply to the export of defense articles previously notified to Congress pursuant to § 123.15 or § 124.11 of this subchapter. For use of the Australian and UK exemptions for congressional notification, see § 126.16(o) and § 126.17(o).

Rose E. Gottemoeller,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2014-30232 Filed 12-24-14; 8:45 am]

BILLING CODE 4710-25-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2010-0573; FRL-9915-60]

RIN 2070-AJ73

Benzidine-Based Chemical Substances; Di-n-pentyl Phthalate (DnPP); and Alkanes, C12-13, Chloro; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA is promulgating a significant new use rule (SNUR) to add nine benzidine-based chemical substances to the existing SNUR on benzidine-based chemical substances. With respect to both the newly-added benzidine-based chemical substances and the previously-listed benzidine-based chemical substances, this rule makes inapplicable the exemption relating to persons that import or process substances as part of an article. EPA is also promulgating a SNUR for di-n-pentyl phthalate (DnPP) and a SNUR for alkanes, C₁₂₋₁₃, chloro. These actions require persons who intend to manufacture (defined by statute to include import) or process these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing such manufacture or processing. The required notifications will provide EPA with the opportunity to evaluate activities associated with a significant new use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs. EPA is also making a technical amendment to the codified list of control numbers for approved information collection

activities so that it includes the control number assigned by the Office of Management and Budget (OMB) to the information collection activities contained in this rule.

DATES: This final rule is effective February 27, 2015.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0573, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), EPA Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Sara Kemme, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 566-0511; email address: kemme.sara@epa.gov.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

These three different SNURs may apply to different entities. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities.

1. *Benzidine-based chemical substances.* You may be potentially affected by this action if you manufacture (defined by statute to

include import), or process, including as part of an article, any of the benzidine-based chemical substances listed in Tables 1 and 2 of the regulatory text in this document. Potentially affected entities may include, but are not limited to:

- Manufacturers or processors of one or more of the subject chemical substances.
- Entities which plan to use the listed chemical substances in conjunction with apparel and other finished products made from fabrics, leather, and similar materials.
- Entities which plan to use the listed chemical substances in conjunction with paper and allied products.
- Manufacturers or processors of the subject chemical substances in printing inks. These entities may include those described by the NAICS codes 325—chemical manufacturing, 31—textile manufacturers, 316—leather and allied products manufacturers, 322—paper manufacturers, 4243 apparel, piece goods, and notions wholesalers, or 443—clothing and accessories stores.

2. *DnPP.* You may be potentially affected by this action if you manufacture (defined by statute to include import), or process DnPP. Potentially affected entities may include, but are not limited to: Chemical industry—plastic material and resins (NAICS code 325211).

3. *Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6).* You may be potentially affected by this action if you manufacture or process the following short-chained chlorinated paraffin (SCCP): Alkanes, C₁₂₋₁₃, chloro (CAS No. 71011-12-6). Potentially affected entities may include, but are not limited to: Manufacturers of SCCPs (NAICS codes 325 and 325998), chemical manufacturing; including miscellaneous chemical product and preparation manufacturing; and processors of SCCPs (NAICS codes 324 and 324191), petroleum lubricating oil and grease manufacturing.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import

certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 for SNUR-related obligations and with respect to benzidine-based chemical substances, the applicability provisions in Unit V. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What action is the agency taking?

In a **Federal Register** proposed rule published on March 28, 2012 (77 FR 18752) (FRL-8865-2), EPA proposed three chemical specific SNURs being addressed in this final rule (Ref. 1). EPA's response to public comments received on the proposed rule appears in Unit X. Please consult the March 28, 2012 **Federal Register** proposed rule (Ref. 1) for further background information for this final rule.

These final SNURs will require persons to notify EPA at least 90 days before commencing the manufacture (including import) or processing of:

- The nine benzidine-based chemical substances identified in Table A of Unit II., which are being added to 40 CFR 721.1660 with a designation of any use as a significant new use;
- DnPP with a designation of any use other than as a chemical standard for analytical experiments as a significant new use; and
- Alkanes, C12-13, chloro (CAS No. 71011-12-6) with a designation of any use as a significant new use.

In addition, this final rule amends the SNUR at 40 CFR 721.1660 to make inapplicable the exemption at 40 CFR 721.45(f) for persons that import or process benzidine-based chemical substances as part of an article. For the benzidine-based chemical substances, the elimination of the article exemption at 40 CFR 721.45(f) will require persons to notify EPA at least 90 days before commencing processing or importing as part of an article any of the newly-added benzidine-based chemical substances, as well as those already covered (61 FR 52287, October 7, 1996 (FRL-5396-6), codified at 40 CFR 721.1660) (Ref. 2).

D. Why is the agency taking this action?

These SNURs are necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of these chemical substances for new uses that may produce changes in human and environmental exposures.

The rationale and objectives for this SNUR are explained in Unit III.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substances included in this final rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here. In the event that a SNUN is submitted, costs are estimated to be less than \$8,700 per SNUN submission for large business submitters and \$6,300 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country, which is estimated to cost less than \$100 on average per notification. The rule may also affect firms that import or process articles that may contain benzidine-based chemicals, because, while not required by the SNUR, these parties may take additional steps to determine whether benzidine-based chemicals are part of the articles that they are considering to import or process. Since EPA is unable to predict whether anyone might engage in future activities that would require reporting, potential total costs were not estimated.

II. Overview of the Chemical Substances Subject to This Rule

The SNURs in this final rule involve certain benzidine-based chemical substances in the existing SNUR at 40 CFR 721.1660 (Ref. 1), the nine benzidine-based chemical substances listed in Table A of this unit, DnPP (CAS No. 131-18-0), and alkanes, C12-13, chloro (CAS No. 71011-12-6).

TABLE A—NEWLY ADDED BENZIDINE-BASED CHEMICAL SUBSTANCES

CAS or accession No.	C.I. name	C.I. No.	Chemical name
117-33-9	Not available	Not available	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[2-[4'-[2-(4-hydroxyphenyl)diazanyl][1,1'-biphenyl]-4-yl]diazanyl]-.
65150-87-0	Not available	Not available	1,3,6-Naphthalenetrisulfonic acid, 8-hydroxy-7-[2-[4'-[2-(2-hydroxy-1-naphthalenyl)diazanyl][1,1'-biphenyl]-4-yl]diazanyl]-, lithium salt (1:3).
68214-82-4	Direct Navy BH	Not available	2,7-Naphthalenedisulfonic acid, 5-amino-3-[2-[4'-[2-(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)diazanyl][1,1'-biphenyl]-4-yl]diazanyl]-4-hydroxy-, sodium salt (1:2).
72379-45-4	Not available	Not available	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[4'-[2-[2-hydroxy-4-[(2-methylphenyl)amino]phenyl]diazanyl][1,1'-biphenyl]-4-yl]diazanyl]-6-(2-phenyldiazanyl)-.

TABLE A—NEWLY ADDED BENZIDINE-BASED CHEMICAL SUBSTANCES—Continued

CAS or accession No.	C.I. name	C.I. No.	Chemical name
Accession No. 21808 CAS No. CBI (NA)	CBI	CBI	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy [[[substituted phenylamino] substituted phenylazo] diphenyl]azo-, phenylazo-, disodium salt. (generic name).
Accession No. 24921 CAS No. CBI (NA)	CBI	CBI	4-(Substituted naphthalenyl)azo diphenylazo-substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name).
Accession No. 26256 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo-substituted carbopolycycloazo benzenesulfonic acid, sodium salt. (generic name)
Accession No. 26267 CAS No. CBI (NA)	CBI	CBI	4-(Substituted phenyl)azo biphenyl azo-substituted carbopolycycle azo benzenesulfonic acid, sodium salt. (generic name).
Accession No. 26701 CAS No. CBI (NA)	CBI	CBI	Phenylazoaminohydroxynaphthalenylazobiphenylazo substituted benzene sodium sulfonate. (generic name).

CAS = Chemical Abstracts Services. CBI = Confidential Business Information. CBI (NA) = Confidential Business Information (Not Available). C.I. = Chemical Index.

III. Rationale and Objectives

A. Rationale

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to issue a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

1. *Benzidine-based chemical substances.* As described in the proposal (Ref. 1), EPA is concerned about potential carcinogenic effects on workers and consumers from the manufacture, processing, or use of these substances. Consumers exposed via dermal exposure to consumer products containing the benzidine-based chemical substances are a particular concern because enzymes present in the human body and in bacteria on the skin aid in the reduction of these chemical substances to the benzidine unit, an established human carcinogen (Ref. 3). The main consumer products that could result in dermal exposure if containing these chemical substances include textiles and leather products because they are in prolonged contact with human skin.

During the review of information on benzidine-based chemical substances, EPA determined that the newly identified chemical substances that are being added to 40 CFR 721.1660 by this final rule present the same concerns (Ref. 4) as those of the benzidine-based chemical substances already listed in the rule ((Ref. 2)), codified at 40 CFR 721.1660). EPA does not believe there is any current use of these nine benzidine-based chemical substances within or outside the United States. This conclusion is based on a review of EPA's own Inventory Update Reporting (IUR) data, and more recent Chemical Data Reporting (CDR) data as well as other sources including the Colour Index International, published by the Society of Dyers and Colourists and American Association of Textile Chemists and Colorists; IHS Chemical Economics Handbook, Dyes; and ICIS Directory of World Chemical Producers.

In addition, as discussed earlier, although some of the benzidine-based chemical substances subject to the 1996 SNUR may be manufactured or processed outside the United States, an analysis of the benzidine-based chemical substances market (Ref. 4) revealed no information indicating import of articles containing benzidine-based chemical substances for non-excluded purposes.

Although it appears there is no ongoing domestic manufacture of the nine newly added benzidine-based chemical substances, or import for a non-excluded use of articles containing any benzidine-based chemical substances, the manufacture (including import) or processing of the nine newly added benzidine-based chemical substances and the import or processing of articles containing any benzidine-based chemical substances may begin at any time, without prior notice to EPA.

Thus, EPA is concerned that commencement of the manufacture (including import) or processing for any new uses, including resumption of past uses, of benzidine-based chemical substances could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist currently. EPA is concerned that such an increase should not occur without an opportunity for the Agency to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance.

Accordingly, EPA is finalizing a SNUR for the nine benzidine-based chemical substances by adding them to those currently listed at 40 CFR 721.1660, and making inapplicable the article exemption at 40 CFR 721.45(f) for those chemical substances newly added in this rulemaking as well as for those already listed at 40 CFR 721.1660. This final rule will require persons who intend to manufacture (including import) or process any of the benzidine-based chemical substances for a non-excluded use, including importing or processing any listed benzidine-based chemical substance for a non-excluded use as part of an article, to submit a SNUN.

2. *DnPP.* As described in the proposal (Ref. 1), EPA has concerns regarding potential adverse human health and environmental effects that may be caused by DnPP. EPA has direct information from animal studies that DnPP specifically can elicit developmental/reproductive effects that are relevant to human health and also indicate potential effects in wildlife. EPA also is concerned that due to its general structure and categorization as a phthalate that DnPP may elicit adverse environmental effects similar to those

described for other phthalates. EPA is concerned that any manufacturing (including import) or processing of DnPP, beyond that for its limited ongoing use as a chemical standard for laboratory use, could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist currently. EPA is concerned that such an increase should not occur without an opportunity to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance. Accordingly, EPA is finalizing a SNUR for DnPP that would designate, as a significant new use, any use of the chemical substance other than use as a chemical standard for analytical experiments. A person who intends to manufacture or process DnPP for use other than use as a chemical standard for analytical experiments would be required to submit a SNUN.

3. *Alkanes, C12-13, chloro (CAS No. 71011-12-6)*. As described in the proposal (Ref. 1), EPA has a primary concern regarding adverse environmental effects that may be caused by alkanes, C12-13, chloro (CAS No. 71011-12-6), one type of SCCP. For example, alkanes, C12-13, chloro, have been shown to be highly toxic to aquatic invertebrates following acute and chronic exposures and to fish following chronic exposures. EPA also has concerns about the persistence and bioaccumulation potential of SCCPs, including alkanes, C12-13, chloro, since these substances have been measured in a variety of biota (*i.e.*, freshwater aquatic species, marine mammals, and avian and terrestrial wildlife) and have also been measured in human breast milk from Canada and the United Kingdom. The mechanisms or pathways by which SCCPs, including alkanes, C12-13, chloro (CAS No. 71011-12-6), move into and through the environment and humans are not fully understood, but are likely to include releases from manufacturing of the chemicals, manufacturing of products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (*e.g.*, disposal, recycling).

EPA believes that all manufacture and processing into the United States of alkanes, C12-13, chloro (CAS No. 71011-12-6) has ceased. Given that EPA has no evidence to suggest that there is any manufacture or processing of this chemical substance in the United States, and taking into consideration the negative commercial and regulatory environment associated with this

chemical internationally (including the European Union (EU) and Canadian ban on marketing) and use of the alkanes, C12-13, chloro (CAS No. 71011-12-6) domestically, EPA does not expect to find such activity. However, EPA is concerned that commencement of the manufacture or processing for any new uses, including resumption of past uses, could significantly increase the magnitude and duration of exposure to humans over that which would otherwise exist. EPA is concerned that such an increase should not occur without an opportunity to evaluate activities associated with a significant new use and an opportunity to protect against potential unreasonable risks, if any, from exposure to the chemical substance. Accordingly, EPA is finalizing a SNUR for alkanes, C12-13, chloro (CAS No. 71011-12-6) that designates as a significant new use any use of the chemical substance. This SNUR requires a person who intends to manufacture or process alkanes, C12-13, chloro (CAS No. 71011-12-6) for any use to submit a SNUN.

B. Objectives

Based on the considerations described in the proposal (Ref. 1) and in the response to public comments, EPA expects to achieve the following objectives with regard to the significant new uses that are designated in this final rule:

1. EPA will receive notice of any person's intent to manufacture or process the specified chemicals for the described significant new uses before that activity begins;
2. EPA will have an opportunity to review and evaluate data submitted in the SNUN before the notice submitter begins manufacturing or processing of the specified chemicals for the described significant new use;
3. EPA will be able to regulate prospective uses of the specified chemicals before the described significant new uses occur, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6 or 7; and
4. EPA would receive a notice alerting the Agency to a reversal of an industry trend toward deselecting for a chemical.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human

beings or the environment to a chemical substance.

- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what constitutes a significant new use of the benzidine-based chemical substances, DnPP, and alkanes, C12-13, chloro (CAS No. 71011-12-6) subject to this rule, EPA considered relevant information about the toxicity of these substances, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA has determined that the manufacture or processing, of any of the benzidine-based chemical substances subject to the 1996 SNUR or being newly added to 40 CFR 721.1660 by this final rule, except for ongoing uses specified in 40 CFR 721.1660(a)(2)(i) of the regulatory text in this document, is a significant new use. EPA has also determined that the manufacture or processing of DnPP for any use other than use as a chemical standard for analytical experiments is a significant new use, and the manufacture or processing of alkanes, C12-13, chloro (CAS No. 71011-12-6) for any use is a significant new use.

V. Applicability of the General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6 or 7 to control the activities

on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

However, 40 CFR 721.45(f) (which generally exempts persons importing or processing a substance as part of an article) will not apply to the benzidine-based chemical substances listed at 40 CFR 721.1660 and those added by this final rule. Therefore, a person who imports or processes as part of an article a benzidine-based chemical substance that is covered by this rule would not be exempt from submitting a SNUN.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

VI. Applicability of the Final Rule to Uses Occurring Before the Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376) (FRL-3658-5) (Ref. 5), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin the commercial manufacture or processing of a covered substance as a significant new use have to cease any such activity as of the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. If a person were to meet the conditions of advance compliance under 40 CFR

721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)) and
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, import, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA would take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical. SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- Human exposure and environmental releases that may result from the significant new uses of the chemical substance.
- Potential benefits of the chemical substance.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-

PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of these chemicals and for articles containing any of the benzidine-based chemical substances included in the 1996 SNUR and those newly added by this final rule when imported or processed as part of an article. These economic analyses, which are briefly summarized here, are available in the docket for this rule. EPA added additional information to the economic analysis for the benzidine-based chemical substances in response to public comments.

The costs of submission of a SNUN would be incurred when a company decides to pursue a significant new use of one of these chemicals. In the event that a SNUN is submitted, costs are estimated at approximately \$8,600 per SNUN submission, and include the cost for preparing and submitting the SNUN, recordkeeping, and the payment of a user fee. Businesses that submit a SNUN are either subject to a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). In its evaluation of this final rule, EPA also considered the potential costs a company might incur by avoiding or delaying the significant new use in the future, but these costs have not been quantified.

B. Export Notification

EPA regulations under TSCA section 12(b) (15 U.S.C. 2611(b)) at 40 CFR part 707, subpart D require that, for chemicals subject to a proposed or final SNUR, a company notify EPA of the first export or intended export to a particular country of an affected chemical substance. EPA estimated that the one-time cost of preparing and submitting an export notification to be \$84. The total costs of export notification would vary per chemical, depending on the number of required notifications (*i.e.*, number of countries to which the chemical is exported).

C. Import or Processing Benzidine-Based Chemical Substances as Part of an Article

In the case of the benzidine-based chemical substances, this rule makes inapplicable the exemption relating to persons that import or process substances as part of an article. In the proposed rule EPA preliminarily determined, based on the Agency's market research, that there was no ongoing manufacturing (including import) or processing of these chemical substances for significant new uses as part of articles or otherwise. For the nine newly-added benzidine-based chemical substances, EPA found no evidence of manufacture either domestically or abroad, and thus also no evidence of importation or processing of these chemical substances as part of articles (Ref. 1). For the majority of the 24 previously listed benzidine-based chemical substances, EPA found no evidence of manufacture, either domestically or abroad. While EPA found that some of the previously listed benzidine-based chemical substances were being manufactured domestically for discrete uses that are not subject to this SNUR, EPA found no evidence that these chemical substances were being imported or processed as part of articles (Ref. 1). EPA received no public comments indicating otherwise. Based on the global trend away from using these chemical substances, the fact that they are regulated in numerous jurisdictions, and the absence of public comments indicating their ongoing use for significant new uses, EPA is finalizing its determination that these benzidine-based chemical substances are not being manufactured (including import) or processed for a significant new use as part of articles or otherwise.

However, the rule may affect firms that plan to import or process types of articles that benzidine-based chemicals are potentially a part of. Some firms have an understanding of the contents of the articles they import or process. However, EPA acknowledges that importers and processors of articles may have varying levels of knowledge about the chemical content of the articles that they import or process. These parties may need to become familiar with the requirements of the rule. And, while not required by the SNUR, these parties may take additional steps to determine whether benzidine-based chemicals are part of the articles that they are considering to import or process. This determination may involve activities such as gathering information from suppliers along the supply chain, and/or testing samples of the article itself.

Costs vary across the activities chosen and the extent of familiarity a firm has regarding the articles it imports or processes. Cost ranges are presented in the "Economic Analysis of the Final Significant New Use Rule for Nine Benzidine Based Chemical Substances" (Ref. 4). Given existing regulatory limitations on certain benzidine-based substances both internationally and within the U.S., industry-wide processes, resources that support companies in understanding and managing their supply chains, and evidence showing minimal worldwide availability of the dyes regulated under the SNUR, EPA believes that article importers that choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis as a result of this rule. For those companies choosing to undertake actions to assess the composition of the articles they import or process, EPA expects that in all likelihood, these importers and processors would take actions that are commensurate with the company's perceived likelihood that a chemical substance might be a part of an article they intend to import into the United States and the resources it has available.

X. Response to Public Comment

The Agency reviewed and considered all comments received related to the proposed rule. Copies of all non-CBI comments are available in the docket for this action. A discussion of the major comments germane to the rulemaking and the Agency's responses follow

A. Legal Authority To Make Inapplicable the Exemption for Persons Who Import or Process Chemical Substances as Part of Articles

One commenter suggests that if chemical substances are not exempted from the SNUR at the point they are incorporated into articles, then EPA should consider whether it is inappropriately regulating "articles under the chemical management authorities of TSCA," (emphasis original) inconsistent with Congressional intent in enacting TSCA. The commenter argues further that the regulation of articles is not the primary purpose of TSCA and that such regulation should be addressed by other agencies operating under other statutes such as the Occupational Safety and Health Act of 1970 and the Consumer Product Safety Act of 1972. Another comment raises similar issues.

EPA responded that the SNUR for benzidine-based chemical substances does not regulate articles per se, but rather persons who manufacture or

process these chemical substances, including when the chemical substances are present as part of articles. TSCA clearly contemplates such regulation, as *certain* articles are expressly removed from TSCA jurisdiction at TSCA section 3(2). Indeed, EPA has a long history of regulating chemical substances as part of articles under TSCA. For polychlorinated biphenyls (the only chemical substance specifically addressed in TSCA as it was originally enacted), section 6(e) of TSCA provides authority for EPA to promulgate rules related to polychlorinated biphenyls in articles, such as electrical transformers. Other examples include the regulation of asbestos (40 CFR 763.160) and regulation of manufacturers of consumer products intended for use by children who also manufacture (including import) lead (40 CFR 716.21(a)(8)).

TSCA section 5 provides EPA with authority to regulate chemical substances, including chemical substances that are part of articles.¹ Under this section, EPA has previously regulated persons that import or process chemical substances as part of articles, including articles containing erionite fiber (40 CFR 721.2800) and mercury (40 CFR 721.10068). This is in keeping with the statutory language authorizing the Administrator to designate a "use of a chemical substance as a significant new use" and to require SNUN submissions from persons that intend to manufacture or process a chemical for a designated significant new use. The commenter is incorrect in suggesting that regulation to address chemical substances in articles is beyond the originally intended functions of TSCA. When TSCA was being drafted, legislators characterized it as "a mechanism to protect against dangerous chemical materials contained in consumer and industrial products"; by way of example, the drafters cited "the presence of mercury in such consumer products as paint, home thermometers, sponges, and a variety of other products." S. Rep. No. 94-698, 94th Cong., 2d Sess., 5-6 (1976).

Furthermore, this application of the regulations (to persons who manufacture or process the chemical substance as part of articles) is consistent with legislators' observation, in drafting this section, that:

¹ It should be noted that there is no general SNUN exemption for uses of a chemical substances involving articles and EPA routinely defines significant new uses to include use in articles. The exemption at 40 CFR 721.45(f) relates to a different question: whether the SNUR applies to persons who process or import a chemical substance by processing or importing the substance as part of an article.

[T]he most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized.

H.R. Rep. 94-1679, 94th Cong., 2d Sess., 65 (1976).

When a chemical substance is domestically produced, the substance generally exists in non-article form at the earliest point of commercial production in the United States. When a chemical substance is imported, however, it may in many instances already be part of an article, even at the earliest point that it enters U.S. commerce. By this action, EPA makes importers of specific chemical substances subject to the same SNUN requirements as domestic manufacturers of the same substance, irrespective of whether such import is as part of an article. This action is consistent with the plain text of TSCA 5(a)(1)(B) (generally, “no person may . . . manufacture or process” for a significant new use without proper notice) and with one of the intended goals of TSCA: to hold importers to “the same responsibilities and obligations as domestic manufacturers,” H.R. Rep. No. 94-1341, 94th Cong. 2d. Sess., 12-13 (1976). This action is also consistent with EPA’s identified concerns regarding benzidine-based chemical substances when they are present as part of an article (See Ref. 1, pg. 18756).

Moreover, when originally promulgating the presumptive SNUN submission exemption for persons who import or process chemical substances as part of articles (40 CFR 721.45(f)), EPA did so based on a belief that people and the environment would generally not be exposed to chemical substances in articles. To address those cases where the assumption may not be valid, EPA specifically noted that, “EPA may decide to eliminate one or all of these . . . exemptions [including the exemption for importers and processors of chemicals as part of articles] if EPA decides that review under a SNUR is warranted for specific substances . . . in articles.” (Ref. 6). Thus, while EPA clearly has statutory authority to subject importers and processors of chemical substances in articles to SNUN requirements, they are presumptively excluded by rule at 40 CFR 721.45(f), based on an assumption that people and the environment will generally not be exposed to substances in articles. (Ref. 6). To the extent that potential exposure to a chemical substance as part of an

article contributes to the EPA’s determination pursuant to the factors in section 5(a)(2) of TSCA that the new use is significant (*i.e.*, EPA has reason to anticipate that use as part of an article would raise important questions, related to potential exposure, that EPA should have an opportunity to review before such use could resume or occur), it is appropriate to make the exemption inapplicable.

EPA notes that one of the commenters appears to have conflated the **Federal Register** notice establishing the article importers’ and article processors’ exemption from PMN requirements (Ref. 7), discussing 40 CFR 720.22(b)) with another **Federal Register** notice establishing the comparable exemptions from SNUR requirements (Ref. 6), discussing 40 CFR 721.45(f)). While EPA recognizes that parts 720 and 721 deal with many similar issues, they are also distinct from each other in important respects. It is significant that in the 1984 action, whereby EPA established the article importers’ and article processors’ exemption for SNURs, it did not simply mirror the 1983 rationale for the comparable exemption from PMN obligations. For PMNs, EPA noted the difficulties associated with determining the identity and Inventory status of each chemical substance in imported articles (*e.g.*, automobiles) (Ref. 7). But for SNURs, EPA placed special emphasis on its assumption that import of the substance as part of an article would not affect human or environmental exposure to the substance, while taking particular care to reserve ongoing discretion to revise its assumption as warranted in the case of specific substances. EPA had reason to differentiate between the two rationales. SNURs are for specified chemical substances for which EPA has identified exposure-based concerns for the defined significant new use (per the TSCA section 5(a)(2) factors). By contrast, PMNs are required for all new chemicals (*i.e.*, those not on the TSCA inventory), not a specified set of chemicals.

Finally, there is no basis for the commenter’s suggestion that EPA should decline to review significant new uses, in deference to the Occupational Safety and Health Administration (OSHA) or the Consumer Product Safety Commission (CPSC), simply because a significant new use notice would be submitted by a person who imports or processes the chemical substance as part of an article. Neither the Occupational Safety and Health Act of 1970 nor the Consumer Product Safety Act of 1972 contains a comparable mechanism to ensure

advance notice and opportunity to review significant new uses of chemical substances, as part of articles or otherwise.

B. Development of a Separate Policy Framework for Making Inapplicable the Exemption for Persons Who Import or Process Chemical Substances as Part of Articles

1. *Comment.* Some commenters suggest that before finalizing a rulemaking to make the “articles exemption” inapplicable to the benzidine-based chemical substances, the EPA should complete a separate public comment process to develop a general “policy framework for the issuance of article SNURs.” Commenters suggest that this policy framework should include science based criteria, feasibility criteria, costs, and other factors.

One comment suggests that, in formulating the “policy framework” or criteria for making the exemption for importers and processors of chemical substances as part of articles inapplicable, EPA should address the following questions:

- Can the risk posed by the chemical of concern be addressed through the standard regulation?
- Why is the standard approach for SNURs that exempts articles not sufficient?
- What conditions make direct regulation of articles necessary?
- What gaps in health and environmental protection are likely to occur if a SNUR only regulates chemicals and mixtures?

Response. The comments conflate two separate issues: The determination of a significant new use under TSCA section 5(a)(2), and the decision to make the regulatory exemption at 40 CFR 721.45(f) inapplicable. (40 CFR 721.45(f) provides that persons who import or process a chemical substance as part of an article are not subject to the notification requirements at 40 CFR 721.25; this exemption is referred to as the “articles exemption” by some commenters). EPA first makes a determination on whether a use of a chemical substance is a significant new use considering the factors listed in TSCA section 5(a)(2). Once that determination is made, EPA separately determines whether it would be appropriate to revoke the regulatory exemption at 40 CFR 721.45(f) for persons who import or process a chemical substance as part of an article.

EPA notes that there may be a variety of cases in which it may be appropriate for EPA to include persons who import or process the chemical substance as

part of an article among the persons subject to SNUN submission obligations. Knowledge regarding chemical exposures from articles has evolved since the Agency established the exemption at 40 CFR 721.45(f) in 1984, and there has been a steady increase in international trade of chemicals in articles. Accumulated data illustrate that SNURs (and section 5(e) consent orders) that include the exemption for persons who import or process a chemical substance as part of an article are sometimes insufficient to appropriately flag significant new exposures from downstream uses. For example, there have been instances in which a section 5(e) consent order for a new chemical substance was issued, prohibiting the release of the chemical substance to water, and yet the chemical substance at issue was later found in the environment and biota. The presence of the chemical substance in the environment and in biota then appears to be associated with the use of the substance in articles (Ref. 8). There are also documented exposures (and resulting toxicity) of children to lead and cadmium and their compounds from a variety of articles, such as toys (Ref. 9), and exposures to other heavy metals from articles, as measured in indoor air and house dust samples, which are direct routes of exposure accounting for children's levels and toxicity (Ref. 10). Other well-documented examples are the presence of brominated flame retardants (e.g., polybrominated diphenyl ethers and brominated phthalates and benzoates) in samplings of articles, indoor air, people, and house dust. The low exchange rate of indoor air and house dust to sources outside the home support the flame retardant release from articles postulate. Likewise, other semi-sealed environments, such as automobiles, have demonstrated migration of flame retardants from treated articles to interior surfaces and indoor air, as no other source was possible. In addition, high flame retardant levels have been observed in biota raised in proximity to articles and living near article recycling sites. Further, observed flame retardant levels in biota and in the environment at locations remote from manufacturing sites suggest transport of these non-volatile chemical substances on associated particulate matter from distributed treated articles, which strongly suggest release from articles as one potential source (Ref. 11–15).

The information discussed in this unit—the well-documented exposures (and resulting toxicity) of children to lead, cadmium, and other metals from a

variety of articles; the data on other chemicals used in articles; and the presence in the environment and biota of certain brominated flame retardants (e.g., polybrominated diphenyl ethers and brominated phthalates and benzoates)—all illustrate that there can be exposure to the chemicals associated with their presence in articles (Refs. 9–15).

The scope of the suggested criteria (which the commenters suggest EPA should now develop to govern its exercise of its authority to make the exemption at 40 CFR 721.45(f) inapplicable) is incommensurate with the level of analysis supporting the original development of the exemption. EPA notes that TSCA section 5(a)(1) establishes a general prohibition on manufacturing or processing a chemical substance for a significant new use without prior notice to EPA. 40 CFR 721.45(f) establishes an exemption from this prohibition, but it is based on a fairly minimal rationale: “EPA believes people and the environment will generally not be exposed to substances in articles.” (Ref. 6). EPA counterbalanced its reliance on this generalized assumption (about all chemicals that exist as part of articles) with a broad reservation of case-by-case discretion to make the exemption inapplicable as “warranted for specific substances.” (Ref. 6).

EPA does not think that development of a “policy framework” is necessary before reaching the conclusion, with respect to benzidine-based chemical substances, that persons who import or process these substances as part of articles should be subject to the notification provisions of 40 CFR 721.25. Dermal exposure can occur from the leaching of the benzidine-based chemical substances by sweat in contact with the dyed textiles (Ref. 11). In addition, data indicate that exposure to other chemicals in materials such as textiles and foam can result from the dust that is generated from abrasion and/or degradation of the materials (Ref. 16). EPA notes that the commenter did not offer data to undercut the conclusion that such exposure can occur. Because of this information, and other information described in Unit III.E. of the (Ref. 1), EPA does not assume that new types or forms of exposure associated with new use of benzidine-based chemical substances would be insignificant merely because the chemical substance is imported or processed as part of an article. Thus, EPA does not believe the default assumption used to support 40 CFR 721.45(f) (that people and the environment will generally not be

exposed to substances in articles) holds with respect to benzidine-based chemical substances.

2. *Comment.* Comments also suggest that EPA analyze the “variety of products” that could be construed as articles, the “practical questions that will arise” if the import and processing of such products were not exempt from SNURs, and the “unique channels of trade,” through which different varieties of products move. Commenters encouraged EPA to develop and articulate publicly a policy framework, considering the following factors on an article-specific basis, before proceeding to revoke the article exemption with respect to a particular chemical substance:

- Whether there is, or will be, direct exposure to the chemical substance in the article during the course of the article's use.
- Whether there is, or will be, a release of the regulated substance, or a metabolite or breakdown product from the substance, during subsequent processing, distribution, use or disposal of the article.
- Whether there is, or will be, a link between import or export of an article and cross-border exposure to the U.S. population.

Response. Given the variety of substances and uses addressed under SNUR regulations, EPA believes it is more efficient to address article-specific issues as they actually arise within each regulatory action than to develop, as suggested by the commenter, an anticipatory “policy framework” document.

The importers and processors of chemical substances present in articles are generally in the best position to know which chemical substances are used in which types of articles. When EPA identifies a particular chemical substance in a SNUR, such stakeholders have an opportunity to identify, in their public comments, any article-specific issues that concern them. Furthermore, these issues are likely to be more accurately identified and more appropriately addressed in connection with the development of a SNUR for particular chemical substances than they would be if they were reviewed generically. In this case, commenters did not raise any issues specific to certain articles.

C. A Compelling Basis Standard for Making Inapplicable the Exemption for Persons Who Import or Process Chemical Substances as Part of Articles

1. *Comment.* Some commenters made the point that revocation of the exemption at 40 CFR 721.45(f) should

not be a presumed component of all SNURs. This was part of a broader comment that EPA should not make this exemption inapplicable unless there was a “compelling basis” to do so. One commenter was concerned that if EPA proceeds on a case-by-case basis, following reasoning that “could be applied to many chemicals,” then elimination of the exemption would come to be a “kind of ‘default’ step” in future SNURs. One commenter also argues that, where the SNUN submission requirement is to apply to importers and processors of substances as part of articles, the TSCA section 5(a)(2) criteria require EPA to undertake a compelling analysis of how the use and distribution of the “specific articles or article categories,” would “contribute to potential exposures of concern.”

Response. As an initial matter, the comments conflate two separate issues: The determination of a significant new use under TSCA section 5(a)(2), and the decision to make the regulatory exemption at 40 CFR 721.45(f) inapplicable. The TSCA section 5(a)(2) factors do not impose a “compelling analysis” requirement on the elimination of the 40 CFR 721.45(f) exemption because (among other reasons) these two actions concern two discrete issues. The section 5(a)(2) factors speak to the significant new use itself. 40 CFR 721.45(f) speaks to who is required to notify EPA of the significant new use.

In this case, EPA identified its reasons, under the TSCA section 5(a)(2) factor analysis, to anticipate that the new use would pose important new questions related to the substances’ potential to threaten health or the environment (Ref. 1, pg. 18756), and that EPA should have an opportunity to consider those questions before such use could occur. (In essence, a SNUR puts a particular set of uses on the same footing as a new chemical, which is subject to automatic review under TSCA section 5(a)(1) unless EPA specifically excludes it from such review.) EPA also identified a basis, specific to benzidine-based chemical substances, to question the assumption that people and the environment will generally not be exposed to the chemical substances in articles. Therefore, EPA is also making inapplicable the exemption at 40 CFR 721.45(f) for persons who import or process a chemical substance as part of an article. No commenter provided data or other information to undercut the factual basis for either decision.

Neither TSCA nor the implementing regulations for SNURs establish a separate “compelling basis” standard, either with respect to the determination

of a significant new use or with respect to the decision to make the exemption at 40 CFR 721.45(f) inapplicable. Nor have commenters identified a persuasive basis for EPA to adopt such a standard under either scenario.

EPA’s specific action with respect to benzidine-based chemical substances is not, as commenters suggest, tantamount to the presumptive revocation of the SNUN submission exemption for importers and processors of chemical substances as part of articles in all future instances. EPA has not proposed to globally modify or eliminate the SNUR exemption for persons who import or process chemical substances as part of articles. EPA need not presently address the merits of an action it is not presently taking, and did not previously propose to take.

TSCA sections 5(a)(2)(B) and (C) require EPA to consider the extent to which a new use “changes the type or form of exposure” or “increases the magnitude and duration of exposure” before making a determination that a particular use is a “significant new use.” EPA disagrees that it must therefore, as one commenter suggests, conduct a multiplicity of separate significant new use analyses whenever the use under consideration involves an article (*i.e.*, one for each specific article or article category, comparing the relative significance of each particular article or article category). In particular, the commenter’s interpretation of TSCA section 5(a)(2) misconstrues the baseline against which the “newness” and the “significance” of a significant new use are evaluated. As EPA has long maintained, the single analytical baseline is the set of uses that were ongoing “as of the date of publication” of the SNUR proposal. (See *e.g.*, Ref. 1).

Furthermore, the particular analytical standards the commenter suggests are not commensurate with the establishment of a one-time notice requirement intended to give EPA an opportunity to later evaluate the need for testing or other regulatory action under TSCA. Requiring upfront answers to the very questions EPA would evaluate after receiving a significant new use notice, as a pre-condition of requiring the notices, would undermine the statutory authorization to issue SNURs in the first place. EPA’s decision to propose a SNUR for a particular chemical use and to make the exemption at 40 CFR 721.45(f) inapplicable to that SNUR need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency is acting because it has reason to anticipate that such use would raise

important new questions related to the substance’s potential to threaten health or the environment, and that EPA should have an opportunity to consider those questions before such use could occur. Since the use designated as a significant new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the significant new use, in articles or otherwise, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

Even if it were appropriate to construe the decision to make the 40 CFR 721.45(f) exemption inapplicable as a subcomponent of the significant new use determination under section 5(a)(2) (rather than as a subsequent determination), EPA adequately considered the section 5(a)(2) factors.

The first factor is the “projected volume of manufacturing and processing of a chemical substance” (TSCA section 5(a)(2)(A)). EPA projects that these substances will not be manufactured or processed at any volume for the new uses in question and notes that for the newly proposed nine benzidine-based chemical substances, data reported to EPA for the 2012, 2006, 2002, and 1998 reporting cycles, as required by the TSCA IUR rule, indicate no evidence of manufacture (including import) (Refs. 1 and 17). Any increase in the projected volume of manufacturing (including import) or processing of these substances, beyond the very limited uses currently ongoing, would reflect a significant departure from prior trends. Given that these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that information presented in the SNUN on the quantities manufactured (including imported) and processed of benzidine based chemical substances would be important to EPA’s overall evaluation of whether the new use may present an unreasonable risk to human health or the environment. The necessary increase in volume of this substance from any new use weighs in favor of determining that the new use is a significant new use.

The second factor is “the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance” (TSCA section 5(a)(2)(B)). For the newly added benzidine-based chemical substances, a general market review on

these chemical substances indicates no current manufacture within or outside the United States. Although some of the chemical substances subject to the 1996 SNUR may still have certain limited ongoing uses (e.g., as a test reagent, lab standard, or microscopy stain), such uses are expected to be confined to limited laboratory or technical applications that are not expected to represent an appreciable amount of overall exposure. Furthermore, EPA did not find evidence of actual ongoing importation or domestic production for these uses. No comments provided evidence of ongoing manufacture (including import) or processing of these chemical substances as part of articles or otherwise. Thus, EPA believes that there is no, or almost no, current exposure to these chemical substances in the United States.

Should a significant new use be planned, EPA anticipates that the new use would raise important new questions such as the following:

- To what extent would the use be expected to involve dermal contact with the substance?
- Would the substance be used in a setting where oral exposure is likely (e.g., would young children be able to mouth the article)?
- How would potential occupational exposures and releases to the environment over the substance's lifecycle be expected to be managed?

Given that these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that the answers to such questions would be important to EPA's evaluation of whether the new use may present an unreasonable risk to human health or the environment. The potential for a new use to change the type or form of exposure weighs in favor of determining that the new use is a significant new use.

The third factor is "the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance" (TSCA section 5(a)(2)(C)). Should one of the designated significant new uses be planned, EPA anticipates that the planned new use would raise important new questions relating to the concentration in which the substance would be used, the potential for repeated exposure, and the potential for continuous exposure. Given these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that the answers to these questions would be important to EPA's overall evaluation of

whether the new use may present an unreasonable risk to human health or the environment. EPA also notes that dermal exposure can occur from the leaching of the chemical substances by sweat in contact with the dyed textiles (Ref. 1). Because of this information, and the information described in Unit III.E. of the proposal (Ref. 1), EPA does not assume that new types or forms of exposure associated with new use of these substances would be insignificant merely because they relate to new use in an article or because the pertinent manufacturing or processing of the substance occurred as part of an article. The potential for activities related to a new use to increase the magnitude and duration of exposure weighs in favor of determining that any non-ongoing use is a significant new use.

The fourth factor is "the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance" (TSCA section 5(a)(2)(D)). EPA anticipates that any new use, beyond the very limited uses currently ongoing, would raise important new questions such as the following:

- To what extent can the anticipated manufacturing, processing, distribution in commerce, and disposal of the chemical substance be expected to result in worker exposure, user exposure, or release of the chemical substance to the environment?
- What potential controls are available to limit such releases?

Given these chemical substances are anticipated to metabolize to the parent benzidine molecule, which is a known human carcinogen, EPA anticipates that the answers to these questions would be important to EPA's overall evaluation of whether the new use "may present an unreasonable risk to human health or the environment." The potential for manufacturing, processing, distribution in commerce or disposal of these benzidine-based chemical substances to change the overall exposure picture weighs in favor of determining that consumer textile use is a significant new use.

After considering each of the four TSCA 5(a)(2) factors, EPA has concluded that the factors taken together weigh in favor of determining that manufacture or processing of these benzidine-based chemical substances for any non-ongoing use would be a significant new use such that the Agency should have an opportunity to analyze the new use before such use (and potential exposures) occurs. This determination would still hold even if one were to consider the 40 CFR

721.45(f) exemption as a subcomponent of the significant new use determination under section 5(a)(2).

D. Narrowing the Scope of SNURs Where the Exemption for Importers and Processors of Chemical Substances as Part of Articles Is Made Inapplicable

Some comments suggest that significant new uses should not be "open-ended" but instead must be targeted to specific articles, particularly in cases where the exemption at 40 CFR 721.45(f) is made inapplicable. The concern expressed is that if the SNUN applies to "any use of a substance, then regulated parties and the EPA would be obligated to proceed through the SNUR process for an article that would have little relevance to the perceived hazard that drove the original SNUR." The commenter further writes that "open-ended article SNUR's can trigger reviews for articles that may have no relationship to the hazard or exposure concerns that motivated EPA's decision to initiate the rule."

EPA's concern with these benzidine-based dyes is not limited to certain exposure pathways to specific articles. EPA's concern is specific to the benzidine-based dyes and thus to the range of exposures that could occur for these chemical substances. The preamble of the proposed rule notes multiple potential routes and sources of exposure including inhalation, skin absorption via dyed textiles, and ingestion. (Ref. 1). Furthermore, SNURs need not be narrowly focused on the mitigation of currently foreseeable exposure scenarios—it is proper that they will also ensure EPA has timely notice of future (and currently unforeseeable) exposure scenarios. An additional requirement to make targeted predictions of the particular uses that "may be proposed in the future" would undermine this intended function of the SNUR.

More generally, an exhaustive list of all applications that could possibly fall within the ambit of a significant new use definition is not a prerequisite for issuing a SNUR. Since the significant new use does not currently exist, deferring a detailed consideration of potential risks related to the importation or processing of these chemical substances (including as part of articles) is an effective use of resources. If a person decides to begin importing or processing the chemical, as part of an article or otherwise, the notice to EPA allows EPA to evaluate the significant new use according to the specific parameters and circumstances surrounding that intended use.

E. EPA Should Have a Reasonable Basis To Conclude That Identified Articles Would Be Distributed in the United States

One comment states that “EPA presents an exposure-based rationale for why certain articles could be a concern, but indicates that there is no current expectation that these chemical substances will be used in such articles.” The commenter believes that before issuing an article SNUR, EPA should have a reasonable basis to conclude that identified articles of concern would be distributed in the United States. The commenter contends that EPA should identify an article containing such a chemical that is currently in global commerce and explain why it is likely to be distributed in the United States. The commenter believes that it might also be possible to identify an article at the research and development stage that is likely to proceed to commercial development. Without such findings, however, the commenter is concerned that EPA would be issuing an article SNUR for a situation that presents no current or likely future threats to health or the environment, and thus that the rule would be a waste of public resources. Another comment raises similar issues, arguing that EPA should provide even more specific information on how the significant new uses contribute to risk.

Alternatively, the first commenter suggests that EPA include a specific provision suspending enforcement of the SNUR until a determination is made that there is a reasonable basis to believe that an article containing the specific chemical had been, or would be, distributed in the United States.

EPA disagrees with the suggestion to limit the application of SNUR submission requirements for importers and processors of the chemical substances as part of articles to situations where importation or processing as part of an article is known to be imminent. SNURs address situations in which EPA is concerned about the potential for use to commence without prior opportunity for review and risk management action where appropriate. For purposes of SNURs, EPA cannot be expected to predict specific situations where new uses may be imminent, or how those specific uses may contribute to risk, before designating significant new uses. The purpose of a SNUR is to obtain such information so that EPA can evaluate risks associated with, and take risk management action where appropriate regarding, any notified activities. These rules serve the important function of

alerting EPA when a significant new use is intended. Without them, EPA would have no expectation of timely identification of new uses of these chemicals. Notice relating to the import or processing of articles is particularly important in this case, as the proposal specifically identified a concern related to the potential for dermal exposure via dyed articles (*i.e.*, from the leaching of the benzidine-based chemical substances by sweat in contact dyed articles, such as textiles). (Ref. 1).

It would not be an efficient use of government resources for EPA to continually monitor global commerce to try to predict which chemicals are about to be imported as part of articles (but have not yet been imported) into the United States. Persons who wish to manufacture (including import) or process these chemical substances for a significant new use, as part of an article or otherwise, are in a better position than EPA to evaluate when they are about to initiate a particular significant new use.

Given that SNURs cannot be issued for ongoing uses, the commenter's suggestion (that EPA must itself make an upfront demonstration that a particular new use is *about to begin*, to secure the opportunity to be notified of when significant new uses involving importation or processing of chemical substances as part of articles are about to begin) is impracticable. It would likely result in a scenario in which an otherwise significant new use would be allowed to commence prior to the issuance of a SNUR proposal, thereby placing that use outside of EPA's SNUR authority. Furthermore, EPA has already considered and rejected (in 2006, following public comment on a 2004 proposal) the position that it must defer revocation of the 40 CFR 721.45(f) exemption for a SNUR until it appears likely “that these chemical substances will be imported as part of articles.” (Ref. 18). EPA concluded in 2006, after a re-evaluation of the issue prompted by public comments, that “if the subject substances when imported as a part of articles are not subject to the SNUR, EPA could miss the opportunity to obtain notifications that would provide information of potential regulatory and assessment value.” (Ref. 19) (ultimately declining to make the exemption inapplicable, based on a separate concern that the use with respect to articles appeared to be already ongoing).

Finally, for essentially the same reasons as set forth in this unit, EPA believes it would be inappropriate to follow one commenter's alternative suggestion: To promulgate a SNUR

without the exemption for importers and processors of chemical substances as part of articles, while somehow “suspending enforcement” until the precise moment that manufacture or processing for a significant new use as part of an article is about to begin, but has not yet begun.

In sum, EPA believes commenter's suggestions would turn the regulatory process on its head. EPA would likely need to already have a SNUR in place in order to obtain the kind of timely information about significant new use that the commenter asserts should be prerequisite to issuing the SNUR in the first place.

F. Intended Coverage of the Benzidine-Based Chemical Substances SNUR

1. *Comment.* One commenter writes that “A proposed rule offering a clear explanation of what uses EPA intends to cover, including an explanation of the alternatives if certain situations are unclear, will greatly increase the chances that useful information about business practices and common terms of art in an industry will be identified.” EPA should define the scope of the uses to be regulated as clearly and precisely as possible.

The commenter also contended that soliciting public comment on the appropriate scope of new uses to be regulated, for a specific chemical substance, constitutes “an abdication of the role that EPA should be undertaking.” The commenter suggests that before soliciting public comments, EPA should have first pursued an informal coordination with downstream industries and (as necessary) an exercise of its “ample authority under TSCA, either through regulatory action under section 8 or order authority under section 11(c).” Finally, the commenter suggests that to the extent the proposed significant new uses admit ambiguity or potential need for adjustment in response to public comment, that is evidence that EPA “should have learned more about the uses” before issuing the proposal and is improperly seeking “to shift the responsibility to stakeholders.”

Response. The description of the scope of the significant new uses in the benzidine-based chemical substances proposed SNUR and the Agency's basis for the proposal were explicit. The SNUR proposal fairly apprised stakeholders as to the chemical at issue and the particular concerns driving the proposed action. It further indicated that based on information available to EPA, the significant new uses identified are not currently on-going. Stakeholders had an opportunity to oppose any of these preliminary findings by supplying

countervailing information through the rulemaking process itself. Grafting additional pre-proposal steps onto the SNUR rulemaking process would be unnecessarily time-consuming and an unsound use of agency resources. The timelier, less resource-intensive, and more transparent process is for interested stakeholders, through the public comment process itself, to simply provide any pertinent countervailing information they wish to add to the initial collection of information EPA presented in the proposal.

As noted earlier, TSCA section 5(a)(2) does not compel nor contemplate an article by article analysis to identify every conceivable significant new use of a chemical substance. EPA evaluates whether a new use is “significant” consistent with the evidence of Congressional intent underlying the enactment of TSCA. See H.R. Rep. No. 94–1341 at 24 (1976) (“[B]ecause of the nature of a substance, it is possible that any new use of it will be significant. Thus, a potentially dangerous substance which is manufactured for a particular use may, if manufactured for a different use present additional health or environmental problems and consequently there should be notice of the intent to manufacture it for such different use.” H.R. Rep. No. 94–1679 at 66 (1976) (“[T]he conferees intend that any potential threats to health or the environment from the manufacture, processing, distribution in commerce, or disposal of a substance associated with a new use be considered by the Administrator when determining the significance of a new use.”) Finally, a broad construction of the significant new use is particularly appropriate where (as in the case of benzidine-based dyes) any increase in the projected volume of manufacturing (including import) or processing of these substances, beyond the very limited uses currently ongoing, would reflect a significant departure from prior trends.

2. *Comment.* “It does not make sense to issue article SNUR’s [*sic*] for full size machines or structures. An article SNUR should focus on the specific components of more complex machines or structures that involve the chemical of concern.”

Response. The commenter neither explains what the commenter means by “full size,” nor offers any specific evidence to support their general view that new uses of chemical substances in “full size machines or structures,” are any less likely to be significant than new uses of chemical substances in “specific components.” Nor does the commenter indicate why persons who import or process chemical substances

as part of articles would be more likely to be importing or processing the chemical substances for use in “full size” articles. Attempting to define and distinguish between “full size” article uses and other uses, and correlating such distinctions to whether persons are importing or processing these chemical substances as part of articles, would delay the rulemaking and increase its complexity, in a manner that does not seem warranted on the basis of the limited information supplied in the comment.

3. *Comment.* “Chemicals used in articles may sometimes be incorporated into ‘internal’ mechanisms of the article that are unlikely to come into contact with people or be released into the environment during normal use of the article.”

Response. The commenter does not explain why the basis for a SNUR should be limited to those exposures that occur concurrent with the article fulfilling its intended function, when TSCA section 5(a)(2)(D) contemplates that EPA will consider the value of ensuring it has a future opportunity to review the whole life-cycle impact (e.g., “manufacturing, processing, distribution in commerce, and disposal”) of a significant new use of a chemical substance. The exposure to the chemical substance, including when it is in an article, may be larger during disposal or recycling than during the “normal use” of the chemical. Further, chemical substances that are ‘internal’ to an article may still result in exposure if the chemical substance has certain physical-chemical properties (e.g., a relatively volatile chemical used as a plasticizer in interior automobile parts) or due to abrasion of the article (e.g., a dye incorporated into furniture covering.)

Nor does the commenter indicate why persons who import or process chemical substances as part of articles would be more likely than any other manufacturers or processors to be manufacturing or processing for use in the internal mechanisms of articles. Attempting to define and meaningfully distinguish between “internal” article uses and other uses, and correlating such distinctions to whether manufacturing or processing of the substance occurs as part of an article, would delay the rulemaking and increase its complexity, in a manner that does not seem warranted on the basis of the limited information supplied in the comment.

4. *Comment.* “EPA should clarify whether the SNUR applies to articles containing the chemical of concern in a solid, liquid, particle or gaseous form.”

Response. This SNUR applies to the chemical substances regardless of form. To the extent the commenter seeks to continue some aspect of the exemption at 40 CFR 721.45(f), depending on the form of the chemical substance in the article that is being imported or processed, the commenter has not offered any specific support for that proposition, either generally or in any particular case. In the SNUR at issue, EPA does not believe it is prudent to limit the application of the rule based on the form (solid, liquid, or gaseous) of the chemical substances at issue. Chemicals that may have been used in one form during the manufacture of the article may be released from the article in a different physical form. Also, fluids and particles are not covered under the applicable definition of article at 40 CFR 704.3. EPA received no comments suggesting that use of these chemicals in one form or another may not be significant based on the TSCA section 5(a)(2) factors. Moreover, information relevant to a specific form of a chemical substance can be submitted in a SNUN and may be considered by EPA in review of that SNUN in determining whether follow-up action is warranted, and may support EPA’s amendment of the SNUR to limit its scope.

5. *Comment.* “[A] chemical may be present at a very low concentration that is unlikely to be associated with a risk warranting EPA risk management action. . . . EPA should consider whether it can establish a *de minimus* exclusion [from the SNUR].”

Response. EPA notes that the SNUR already contains a general exemption for unintentionally present impurities at 40 CFR 721.45(d). To the extent chemical substances are intentionally added to articles at very low concentrations, the question of whether the substance warrants risk management action is one that EPA can address upon receipt of the SNUN, not an analytical prerequisite to deciding whether it should receive the SNUN in the first place.

G. Screening for Benzidine-Based Chemical Substances

Some commenters faulted the proposal for not identifying precise screening operations to be taken in response to the SNUR, and for not conducting additional analyses of the cost and feasibility of such screening operations. One commenter suggests, in particular, that an article importer should be deemed in compliance with the SNUR if the chemical is present below an established *de minimis* level (based on mass or concentration), or if it simply does not know the article’s